AMENDED IN SENATE AUGUST 31, 2005

CALIFORNIA LEGISLATURE—2005-06 REGULAR SESSION

ASSEMBLY BILL

No. 1317

Introduced by Assembly Member Ruskin (Principal coauthor: Assembly Member Tran)

February 22, 2005

An act to add and repeal Sections 100854 and 100855 of, and to repeal and add Article 3 (commencing with Section 100825) of Chapter 4 of Part 1 of Division 101 of, the Health and Safety Code, An act to add Sections 100827 and 100829 to, to repeal Sections 100831 and 100835 of, and to repeal and add Sections 100825, 100830, and 100832 of, the Health and Safety Code, relating to environmental laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1317, as amended, Ruskin, Environmental laboratories.

Existing law requires a laboratory that performs analysis for regulatory purposes of drinking water, wastewater, air, hazardous waste, and contaminated soils or sediments to obtain certification by the State Department of Health Services or, in the alternative, if appropriate, to obtain accreditation under the National Environmental Laboratory Accreditation Program (NELAP).

This bill would repeal, recast, and reenact *certain of* those provisions.

Among other things, the bill would authorize the department to offer both state accreditation and NELAP accreditation. The bill would set forth the duties and responsibilities of the department in accrediting and monitoring environmental laboratories, and would authorize the department to adopt regulations. It would require the department to appoint a multidisciplinary committee to provide assistance, advice,

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and recommendations to the department regarding technical and scientific aspects of laboratory accreditation. The bill would authorize an administrative hearing when the department denies, suspends, or revokes a laboratory's accreditation.

The bill would require any fees and civil penalties collected pursuant to the bill to be deposited in the Environmental Laboratory Improvement Fund, to be available upon appropriation by the Legislature for purposes of the accreditation program.

Because, in addition to civil penalties, the bill would also impose eriminal penalties for violation of certain of its requirements, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes-no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 100825 of the Health and Safety Code is 2

repealed. 3 100825. (a) Laboratories that perform, for regulatory

purposes, analyses of drinking water, wastewater, air, hazardous wastes, and contaminated soils or sediments, or any combination

of these, shall obtain a certificate pursuant to this article.

Laboratories that perform analyses for pesticide residues in food 8

pursuant to Section 110490 shall also obtain a certificate pursuant to this article. A laboratory may apply for NELAP

10 accreditation in lieu of certification under this article if it chooses

to meet NELAC standards for those fields of testing under 11

12 Section 100862 that are in common with the two programs.

Laboratories meeting the requirements of NELAP accreditation 13

14 pursuant to this article shall become eligible for recognition by

15 other states and agencies that require or accept NELAP 16 accreditation.

(b) In any arrangement between laboratories that involves the transfer of samples or portions of samples, the analyzing -3- AB 1317

laboratory shall be identified in all sample reports and shall be the laboratory for purposes of certification or NELAP accreditation.

- (e) The following definitions apply for the purposes of this article:
- (1) "Accreditation" means the recognition of a laboratory that is approved by a NELAP approved accrediting authority to conduct environmental analyses in those fields of testing specifically designated in Section 100862.
- (2) "Approved third-party laboratory assessor body" means an organization that has been approved as a contractor under NELAC standards to assess environmental laboratories.
- (3) "Certificate" means a document issued to a laboratory that has received certification or accreditation pursuant to this article.
- (4) "Certification" means the granting of approval by the department to a laboratory that has met the standards and requirements of this chapter and the regulations adopted thereunder. Certification shall not include NELAP accreditation.
- (5) "Corrective action report" means a written document signed by or on behalf of a person, entity, or laboratory that states the corrective actions proposed by the person, entity, or laboratory to correct the deficiencies or violations stated in a report of deficiencies.
- (6) "Deficiency" means noncompliance with one or more of the requirements of this article or any rule or regulation adopted thereunder.
- (7) "ELAP" means the State Department of Health Services' Environmental Laboratory Accreditation Program.
- (8) "Laboratory" means any facility or vehicle that is owned by a person, or by a public or private entity, and that is equipped and operated to carry out analyses in any of the fields of testing listed in Section 100860.1 or Section 100862.
- (9) "NELAC" means the National Environmental Laboratory Accreditation Conference, which is a voluntary organization of state and federal officials.
- (10) "NELAC standards" refer to the standards found in EPA publication number 600/R-98/151, November 1998, and any subsequent amendments.
- 39 (11) "NELAP" means the National Environmental Laboratory
 40 Accreditation Program established by NELAC.

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(12) "NELAP accredited laboratory" means a laboratory that has met the standards of NELAC and has been accredited by a primary or secondary NELAP recognized authority.

- (13) "NELAP approved accrediting authority" means a state agency that is authorized by NELAC to accredit laboratories.
- (14) "NELAP recognized primary accrediting authority" means a state or federal agency that is responsible for the accreditation of environmental laboratories within that state.
- (15) "NELAP recognized secondary accrediting authority" means a state or federal agency that grants NELAP accreditation to laboratories based on their accreditation by a NELAP recognized primary accrediting authority.
- (16) "Performance based measurement system" means a set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified and serve as eriteria for selecting appropriate test methods to meet those needs.
- (17) "Pesticide" means any substance that alone, in chemical combination, or in any formulation with one or more substances, is an "economic poison" within the meaning of Section 12753 of the Food and Agricultural Code or a "pesticide" as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).
- (18) "Regulatory agency" means any federal, state, or local governmental agency that utilizes environmental analyses performed by a laboratory regulated under this section.
- (19) "Regulatory purposes" means the use of laboratory analysis required by a regulatory governmental agency for determining compliance with this section or Chapter 6.5 (commencing with Section 25100) of, Chapter 6.7 (commencing with Section 25280) of, and Chapter 6.8 (commencing with Section 25300) of, Division 20, Article 1 (commencing with Section 116270) of, Article 2 (commencing with Section 116325) of, and Article 3 (commencing with Section 116350) of, Chapter 4 of Part 12 of Division 104, or Division 7 (commencing with Section 13000) of the Water Code, or the regulations adopted under any of the provisions set forth in this paragraph.
- 38 SEC. 2. Section 100825 is added to the Health and Safety 39 Code, to read:

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100825. (a) This article shall be known, and may be cited, as the Environmental Laboratory Accreditation Act.

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- (b) Laboratories that perform analyses on any combination of environmental samples, or raw or processed agricultural products for regulatory purposes shall obtain a certificate of accreditation pursuant to this article.
- (c) Unless the express language or context requires otherwise, the definitions in this article shall govern the construction of the article.
- (1) "Accreditation" means the recognition of a laboratory by the department to conduct analyses of environmental samples for regulatory purposes.
- (2) "Assessor body" means the organization that actually executes the accreditation process, including receiving and reviewing applications, documents, PT sample results, and onsite assessments.
- (3) "Certificate" means a document issued by the department to a laboratory that has received accreditation pursuant to this article.
- (4) "Department" means the State Department of Health Services.
- (5) "Environmental samples" means potable and nonpotable surface waters or groundwaters, soils and sediments, hazardous wastes, biological materials, or any other sample designated for regulatory purposes.
- (6) "NELAC" means the National Environmental Laboratory Accreditation Conference.
- (7) "NELAC standards" refers to the requirements found in EPA publication number 600/R-98/151, November 1998, and any subsequent amendments that are adopted by EPA or the national program.
- (8) "NELAP" means the National Environmental Laboratory Accreditation Program established by NELAC.
- (9) "NELAP accreditation" means the accreditation of a laboratory that has met the requirements of the NELAC standards, and the requirements of this article.
- 37 (10) "NELAP accredited laboratory" means a laboratory that 38 has met the standards of NELAC and has been accredited by a 39 primary or secondary NELAP-recognized accrediting authority.

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(11) "NELAP-recognized accrediting authority" means a state agency that is authorized by NELAP to accredit laboratories.

- (12) "NELAP-recognized primary accrediting authority" means a state agency that is responsible for the accreditation of environmental laboratories within that state or that performs the primary accreditation of a lab from a non-NELAP state or where the laboratory's home state does not offer accreditation in a given field of accreditation.
- (13) "NELAP-recognized secondary accrediting authority" means a state agency that is authorized by NELAP to accredit environmental laboratories within that state that have been accredited by a NELAP-approved accrediting authority in another state.
- (14) "Proficiency testing (PT)" is a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.
- (15) "PT sample" means a sample used for proficiency testing.
- (16) "Regulatory purposes" means a statutory or regulatory requirement of a state board, office, or department, or of a division or program that requires a laboratory certified under this article or of any other state or federal agency that requires a laboratory to be accredited.
- (17) "Revocation" means the permanent loss of a certificate of accreditation, including all units and fields of accreditation for state accreditation and all fields of accreditation for NELAP accreditation.
- (18) "State accreditation" means accreditation of a laboratory, that has met the requirements of this article and regulations adopted by the department pursuant to this article.
- (19) "Suspension" means the temporary loss of a certificate of accreditation or a unit or field of accreditation.
- 34 SEC. 3. Section 100827 is added to the Health and Safety 35 Code, to read:
 - 100827. A laboratory accredited by the department shall report, in a timely fashion and in accordance with the request for analysis, the full and complete results of all detected contaminants and pollutants to the person or entity that

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submitted the material for testing. The department may adopt regulations to establish reporting requirements for this section.

- SEC. 4. Section 100829 is added to the Health and Safety Code, to read:
- 100829. The department may do all of the following related to accrediting environmental laboratories in the state:
- (a) Offer both state accreditation and NELAP accreditation, which shall be considered equivalent for regulatory activities covered by this article.
- (b) Adopt regulations to establish the accreditation procedures for both types of accreditation.
 - (c) Retain exclusive authority to grant NELAP accreditation.
- (d) Accept certificates of accreditation from laboratories that have been accredited by other NELAP-recognized accrediting authorities.
- (e) Adopt regulations to establish procedures for recognizing the accreditation of laboratories located outside California for activities regulated under this article.
- (f) (1) Adopt regulations for the collection of laboratory accreditation fees.
- (2) Fees collected under this section shall be adjusted annually as provided in Section 100425. The adjustment shall be rounded to the nearest whole dollar.
- (3) Fees shall be set for the two types of accreditation provided for in subdivision (a).
- (4) Programs operated under this article shall be fully fee-supported.
- SEC. 5. Section 100830 of the Health and Safety Code is repealed.
- 100830. The department shall adopt regulations governing the administration and enforcement of this article. Regulations adopted by the department under this article shall specify conditions for recognizing on the basis of reciprocity the certification or NELAP accreditation of laboratories located outside of the State of California for activities regulated under this article by another state or by an agency of the United States government. Certification by another jurisdiction may be recognized for purposes of this article with regard to one or several program activities, including, but not limited to, onsite

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1 inspections, the analysis of proficiency testing samples, or the evaluation of personnel qualifications.

- 3 SEC. 6. Section 100830 is added to the Health and Safety 4 Code, to read:
- 5 100830. The department may do all of the following:
- 6 (a) Adopt regulations establishing requirements for both types 7 of accreditation. The regulations shall include, but not be limited 8 to, all of the following:
- 9 (1) Laboratory personnel.
- 10 (2) Quality assurance procedures.
- 11 (3) Laboratory equipment.
- 12 (4) Facilities.

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- 13 *(5) Standard operating procedures.*
- 14 (6) Proficiency testing.
- 15 (7) Onsite assessments.
- 16 (8) Recordkeeping.
- 17 (9) Units and fields of accreditation.
 - (b) Adopt regulations establishing conditions under which the department may issue, deny, renew, or suspend a certificate of accreditation for individual units or fields. Suspension and denial of units or fields of accreditation shall be based on a laboratory's failure to comply with this article and regulations adopted thereunder.
- 24 SEC. 7. Section 100831 of the Health and Safety Code is 25 repealed.
 - 100831. NELAP accreditation by another jurisdiction shall be recognized, for purposes of this article, for the granting of accreditation by reciprocity.
- 29 SEC. 8. Section 100832 of the Health and Safety Code is 30 repealed.
- 100832. The department shall adopt or amend the regulations relating to environmental laboratories as necessary to enable California environmental laboratories to participate in the National Environmental Laboratory Accreditation Program.
- 35 SEC. 9. Section 100832 is added to the Health and Safety 36 Code, to read:
- 37 100832. All regulations adopted by the department pursuant
- 38 to this article, as they read immediately preceding January 1,
- 39 2006, shall remain in full force and effect until repealed or
- 40 amended by the department in accordance with the rulemaking

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1 provisions of the Administrative Procedure Act, Chapter 3.5 2 (commencing with Section 11340) of Part 1 of Division 3 of Title 3 2 of the Government Code.

SEC. 10. Section 100835 of the Health and Safety Code is repealed.

100835. (a) The department may adopt regulations for the following:

- (1) Quality assurance programs in effect at the laboratory.
- (2) Laboratory facilities.
- 10 (3) Methods.

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- 11 (4) Equipment.
- 12 (5) Proficiency testing.
- 13 (6) Fields of testing.
 - (7) Qualifications of laboratory directors and other laboratory personnel.
 - (8) Fees, inspections, hearings and other matters necessary to the administration and enforcement of this article.
 - (9) NELAP accreditation.
 - (10) Any other area concerning the operation or maintenance of a laboratory not inconsistent with this article as may be necessary to carry out this article.
 - (b) If any regulations governing the minimum standards for certification or NELAP accreditation, or both, of laboratories that perform analysis of food relate to the testing of raw agricultural commodities or dairy products, those regulations shall be adopted, in cooperation with the Department of Food and Agriculture.

SECTION 1. Article 3 (commencing with Section 100825) of Chapter 4 of Part 1 of Division 101 of the Health and Safety Code is repealed.

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All matter omitted in this version of the bill appears in the bill as introduced in the Assembly, February 22, 2005. (JR11)